

## REMARKS

Entry of the foregoing amendments is respectfully requested.

### **Summary of Amendments**

Upon entry of the foregoing amendments, claims 1-104 are canceled and claims 105-208 are added, whereby claims 105-208 will be pending. Claims 105, 163, 180, 207 and 208 are independent claims. Support for the new claims can be found throughout the present specification and in the canceled claims.

Applicants emphasize that the cancellation of claims 1-104 is without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute these claims in one or more continuation and/or divisional applications.

### **Summary of Office Action**

As an initial matter, Applicants note with appreciation that the Office Action indicates that the claim for priority is acknowledged. However, the Office Action Summary does not clearly indicate that a certified copy of the priority document has been received by the Patent and Trademark Office (none of the boxes is checked). Accordingly, Applicants respectfully request that the receipt of a certified copy of the priority document be clearly acknowledged in the next communication from the Patent and Trademark Office.

Applicants also note with appreciation that signed and initialed copies of the Forms PTO-1449 submitted in the Information Disclosure Statement filed March 9, 2004, the Supplemental Information Disclosure Statement filed April 20, 2004 and the Second

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Supplemental Information Disclosure Statement filed April 19, 2005 have been returned together with the present Office Action.

The Restriction Requirement is made final. Claims 74-77, 79 and 82-104 are withdrawn from consideration.

Claims 59 and 60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12, 15, 20-21, 24-27, 29-32, 35-36, 72, 78 and 81 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2004/0241214 by Kirkwood et al. (hereafter "KIRKWOOD").

Claims 22-23 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over KIRKWOOD.

Claims 13-14, 16-19, 28, 50-60 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD.

Claims 33 and 34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD and further in view of U.S. patent No. 6,903,243 to Burton (hereafter "BURTON").

Claims 37-49 and 61-71, 73 and 80 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD and further in view of U.S. Patent No. 6,333,093 to Burrell et al. (hereafter "BURRELL").

**Response to Office Action**

Withdrawal of the rejections of record is respectfully requested, in view of the foregoing amendments and the following remarks.

***Response to Rejection of Claims under 35 U.S.C. § 112, Second Paragraph***

Claims 59 and 60 (which generally correspond to new claims 161 and 162) are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The rejection essentially alleges that claims 59 and 60 recite the term “size”, but fail to indicate to which dimension the “size” refers too.

This rejection is respectfully traversed. Specifically, new claims 161 and 162 ultimately depend from claim 141 which recites that the composite has a sheet-like structure. Applicants submit that it is immediately clear to one of skill in the art what the “size” (indicated in  $\text{cm}^2$  or  $\text{m}^2$  units) of a sheet-like structure refers to, i.e., the area thereof. Applicants also note that the Examiner has not indicated what alternative meaning “size” in the present context may reasonably be assumed to have.

For at least the foregoing reason, the claim rejection under 35 U.S.C. § 112, second paragraph, is unwarranted, and withdrawal thereof is respectfully requested.

***Response to Rejection of Claims under 35 U.S.C. § 102(e) over KIRKWOOD***

Claims 1-12, 15, 20-21, 24-27, 29-32, 35-36, 72, 78 and 81 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by KIRKWOOD. The rejection essentially

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asserts that KIRKWOOD teaches a wound dressing comprising a liquid-permeable, apertured wound-facing surface with a plurality of particles comprising silver located behind the wound-facing surface. The examiner equates the applied apertured fabric to the mesh structure recited in the rejected claims. Furthermore, the rejection alleges that KIRKWOOD teaches that an absorbent may be located behind the layer of silver particles and that all of the additional elements recited in the rejected claims are disclosed in KIRKWOOD as well. Additionally, the Office Action rejects claim 81 because the applied article may allegedly be used as a diaper and meets the structural and compositional limitations set forth in claim 1.

This rejection is respectfully traversed. Specifically, the present independent claims recite elements which are recited in, e.g., canceled claims 37 and 38 (see also cancelled claims 45 and 46). Also, independent claim 163 is substantially identical to canceled independent claim 61. None of claims 37, 38, 45, 46 and 61 has been rejected as anticipated by KIRKWOOD. At page 7, second paragraph, of the present Office Action, it is expressly acknowledged that KIRKWOOD is silent as to the anti-bacterial silver being provided as a coating, sheet or film between the first and second layers. For this reason alone, none of the claims submitted herewith is anticipated by KIRKWOOD, wherefore withdrawal of the claim rejection under 35 U.S.C. § 102(e) over KIRKWOOD is respectfully requested.

Applicants point out that the cancellation of claim 1 and the other claims rejected as allegedly anticipated by KIRKWOOD is not to be construed as Applicants' admission that the Examiner's arguments with respect to KIRKWOOD are meritorious, and merely is to

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expedite the issuance of a patent with the claims submitted herewith. Applicants intend to prosecute the canceled claims in one or more divisional and/or continuation applications in due course.

***Response to Rejection of Claims under 35 U.S.C. § 103(a) over KIRKWOOD in View of BURELL***

Claims 37-49 and 61-71, 73 and 80 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD and further in view of BURELL. The Office Action acknowledges that KIRKWOOD is silent as to the anti-bacterial silver being provided as a coating, sheet or film between the first and second layers and the incorporation of a layer of aluminum between the silver layer and the first layer. However, the rejection alleges that BURELL teaches a multilayer anti-microbial material formed to produce an interference color, and thus an indicator of antimicrobial effect. According to page 7, last paragraph, of the present Office Action, BURELL provides a base layer of a partly reflective layer (e.g., aluminum) and a top layer containing at least one antimicrobial metal (preferably silver). "The top layer when contacted with an alcohol or water-based electrolyte releases ions of the silver metal into the alcohol or water-based electrolyte at a concentration to provide a localized anti-microbial effect. A color change occurs upon contact with an alcohol or water-based electrolyte so as to indicate activation of the material". The rejection further alleges that "Claim 15 provides for the base and top layer composite to be placed in between the perforated, wound-facing layer and an absorbent layer of a wound dressing with the aluminum base layer facing the perforated layer and the

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top, silver layer facing the absorbent layer.” Sentence bridging pages 7 and 8 of Office Action. The Examiner takes the position that it would have been obvious to one of ordinary skill in the art to modify the antimicrobial wound dressing of KIRKWOOD with the motivation of providing the wound dressing with a visible indicator of anti-microbial activity, so as to minimize the over application of antimicrobial agents and unnecessary wound dressing removal.

With respect to claims 40, 42-44 and 67 the rejection acknowledges that KIRKWOOD and BURRELL are silent as to the amount of silver that is present in the wound dressings and that these documents do also not explicitly teach the claimed liquid-absorbing capacity or the amount of silver that is released over 24 hours, but alleges that these properties can be presumed to be present (inherent) in the composite of KIRKWOOD. Support for said presumption can allegedly be found in the use of like materials, i.e., a two layer absorbent article comprising a liquid permeable layer with an antimicrobial metal in elemental form. Page 8, last two paragraphs of Office Action.

This rejection is respectfully traversed as well. Initially, Applicants note again that independent claims 105, 180, 207 and 208 submitted herewith correspond generally to a combination of independent claim 1 with, *inter alia*, any of claims 37, 38 and 45, and that independent claim 163 is substantially identical with canceled claim 61. All of these independent claims have in common that they generally recite the presence of a coating or layer of antimicrobial metal in elemental form between a first and second layer of an antimicrobial composite. The present Office Action acknowledges that KIRKWOOD neither teaches nor suggests the presence of such a coating or layer of antimicrobial metal

between the layers of the composite disclosed therein. However, the Examiner essentially takes the position that one of ordinary skill in the art would have been motivated to include the indicator composite of BURRELL in the composite of KIRKWOOD, i.e., in such a way that the composite of BURRELL would be arranged between the layers of the composite of KIRKWOOD. For at least the following reasons, this alleged motivation does clearly not exist.

First, the indicator composite of BURRELL serves a dual function, i.e., it is the source of antimicrobial metal and at the same time is to indicate by a color change whether the antimicrobial metal (e.g. silver) has been released from the top layer of the indicator composite. For example, the Abstract of BURRELL states, *inter alia*:

Multilayer anti-microbial materials formed to produce an interference colour, and thus an indic[a]tor of anti-microbial effect, are provided. The materials include a partly reflective base layer and a partly reflective, partly transmissive top layer balanced to produce an interference colour. The top layer is formed from an anti-microbial metal with atomic disorder. Dissolution or a change in composition of the top layer on contacting an alcohol or electrolyte causes a change in optical path length so as to produce a change in the interference colour of the material.

The composite of KIRKWOOD, on the other hand, already contains an antimicrobial substance, wherefore the inclusion of yet another source of antimicrobial substance (i.e., the antimicrobial indicator composite of BURRELL) would not appear to be of any advantage, but only would complicate matters.

In particular, two different sources of antimicrobial substances (the antimicrobial particles of KIRKWOOD and the antimicrobial indicator composite of BURRELL) which release the antimicrobial substances according to different mechanisms and at different rates would require a careful matching of the release profiles in order to insure that the

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resulting composite does not release too much and not too little of the antimicrobial substances per time unit. For this reason alone, there would not be a motivation, but rather a disincentive to include the antimicrobial indicator composite of BURRELL in the antimicrobial composite of KIRKWOOD.

Second, even if one were to assume, *arguendo*, that one of ordinary skill in the art would accept the disadvantage of having two different sources of antimicrobial substance in the same composite in order to be able to benefit from the color changing ability of the antimicrobial composite of BURRELL, this would not result in the composite of the present invention.

In this regard, it is pointed out that BURRELL does not specifically teach or suggest that the antimicrobial composite disclosed therein is to be arranged between two layers of a composite. It is noted that the Examiner relies on claim 15 of BURRELL, alleging that "Claim 15 provides for the base and top layer composite to be placed in between the perforated, wound-facing layer and an absorbent layer of a wound dressing with the aluminum base layer facing the perforated layer and the top, silver layer facing the absorbent layer." Applicants are unable to find a corresponding disclosure in BURRELL.

Specifically, claim 15 of BURRELL reads:

The wound dressing of claim 14, wherein the first layer, includes a coating containing an antimicrobial metal.

Independent claim 14, from which claim 15 depends, reads:

A multi[p]layer, laminated wound dressing, comprising:  
a first, wound facing layer formed of a perforated, non-adherent material;  
a second layer laminated to the first layer, and being formed of an absorbent material;  
an optional third layer laminated to one or both of the first and second layers;  
at least one of the first, second and optional third layers, being formed from a plastic material;



and  
the first, second and optional third layer being laminated together by ultrasonic welds spaced intermittently on the dressing so as to allow the dressing to be cut down in size without causing delamination.

Neither claim 14 nor claim 15 recites a specific arrangement of the “coating containing an antimicrobial metal” of claim 14 with respect to the first layer, let alone mentions a base layer and top layer composite (with an aluminum base layer).

Nothing in BURRELL specifically teaches or suggests arranging the antimicrobial indicator composite thereof between two layers of another (antimicrobial) composite. In fact, that BURRELL is directed to two independent inventions, i.e., the multilayer antimicrobial material recited in claim 1 and the multilayer, laminated wound dressing having ultrasonic welds recited in claim 14 (in this regard, see also Abstract of BURRELL, which Abstract mentions that “Multilayer, laminated wound dressings are also provided”). Claim 17 appears to link these two inventions. However, claim 17 only recites that the first layer of the laminated wound dressing of claim 14 “includes” the multilayer anti-microbial material of claim 1, without reciting any specific arrangement. Claim 18, which depends from claim 17 does recite a specific arrangement, i.e.,

The wound dressing of claim 17, wherein the multi[p]layer anti-microbial coating is provided on both the first and third layers, such that a colour change is delectable on either side of the wound dressing.

Emphasis added.

Accordingly, claim 18 calls for an arrangement wherein the multilayer antimicrobial coating is provided on the outside (i.e., the first and third layers) of the multilayer wound dressing of claim 14. Claim 18 also indicates the reason why it is important to have the multilayer antimicrobial coating on the outside of the wound dressing, i.e., visibility.

In other words, one of ordinary skill in the art will understand that arranging the multilayer antimicrobial indicator composite of BURRELL between any two layers of a wound dressing (or any other multilayered composite) would not make sense, because in this case one would be unable to take advantage of the color changing abilities of the indicator composite. This also is one of the reasons why one of ordinary skill in the art would not be motivated to arrange the multilayer antimicrobial composite of BURRELL between any of the layers of the composite of KIRKWOOD. A corresponding arrangement would not be of any advantage if one wanted to benefit from the color changing abilities of the indicator composite of BURRELL (as noted above, one may assume this to be the only conceivable justification, if any, for including the indicator composite of BURRELL in the composite of KIRKWOOD, despite the apparent disadvantages associated therewith), because in this case, the indicator composite of BURRELL would be covered, thereby making it impossible to monitor its color change and defeating the very purpose of including the composite of BURRELL in the composite of KIRKWOOD.

For at least the foregoing reasons, the antimicrobial composite recited in the present independent claims is not rendered obvious by KIRKWOOD in view of BURRELL. Accordingly, it is respectfully requested to withdraw the claim rejection under 35 U.S.C. § 103(a) over KIRKWOOD and BURRELL.

***Response to Remaining Claim Rejections under 35 U.S.C. § 103(a)***

The additional claim rejections under 35 U.S.C. § 103(a) included in the present Office Action and not already addressed above relate exclusively to dependent claims. As

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set forth above, all of the independent claims submitted herewith are neither anticipated nor rendered obvious by any of the documents cited in the present Office Action. Accordingly, at least for the same reasons as set forth above, the claims dependent from these independent claims are not anticipated and not rendered obvious, either. Thus there appears to be no need to discuss any further reasons why the rejected dependent claims are allowable. However, Applicants' silence in this respect must not be construed as admission that any of the arguments relating to the rejection of the dependent claims set forth in the present Office Action is of merit. For example, many of the rejections of the dependent claims are based on presumptions of inherency. The Examiner has not supported any of the corresponding presumptions by documentary evidence, and for this reason alone, the corresponding rejections are without a sound basis.

### CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

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